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 Warner Chilcott Company, Inc. and  
 Warner Chilcott (US), LLC

**IN THE UNITED STATES DISTRICT COURT  
 DISTRICT OF NEW JERSEY**

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 :  
 WARNER CHILCOTT LABORATORIES :  
 IRELAND LIMITED, :  
 WARNER CHILCOTT COMPANY, INC., :  
 WARNER CHILCOTT (US), LLC and :  
 MAYNE PHARMA :  
 INTERNATIONAL PTY. LTD., :  
 :

Plaintiffs, :

v. :

IMPAX LABORATORIES, INC., :  
 MYLAN PHARMACEUTICALS INC., :  
 MYLAN INC., MUTUAL :  
 PHARMACEUTICAL COMPANY, INC., :  
 UNITED RESEARCH LABORATORIES, :  
 INC. and URL PHARMA, INC., :  
 :

Defendants. :

**Civil Action No.: 2:08-cv-6304-WJM-MF**

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**PLAINTIFFS' REPLY TO THE MUTUAL DEFENDANTS'  
CORRECTED COUNTERCLAIMS**

Plaintiffs Warner Chilcott Laboratories Ireland Limited, Warner Chilcott Company, Inc., and Warner Chilcott (US), LLC, and Mayne Pharma International Pty. Ltd. (collectively “Plaintiffs/Counterclaim-Defendants”) reply to the corrected Counterclaims of Defendants/Counterclaim-Plaintiffs Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc., and URL Pharma, Inc. (collectively “Mutual”) as follows:

### **ANSWER TO CORRECTED COUNTERCLAIMS**

#### **Jurisdiction**

1. This is an action for Declaratory Relief, over which this court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338, and 2201.

**Answer:** Admitted.

2. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

**Answer:** Admitted.

3. An actual, justiciable controversy exists between the parties by virtue of the allegations of Plaintiffs’ Complaint in this action and Defendants’ Answer.

**Answer:** Admitted that there is a justiciable controversy between Plaintiffs/Counterclaim-Defendants and Mutual regarding the alleged invalidity of the ‘161 patent. Denied in all other respects.

**Parties**

4. Counterclaim-Plaintiffs Mutual Pharmaceutical Co., Inc. and United Research Laboratories, Inc. (collectively, “Counterclaim-Plaintiffs”) are corporations organized and existing under the laws of the Commonwealth of Pennsylvania, having principal places of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124.

**Answer:** On information and belief, admitted.

5. Upon information and belief, Counterclaim-Defendant Warner Chilcott Laboratories Ireland Limited (“WCLI”) is a corporation organized and existing under the laws of the Republic of Ireland, having a principal place of business at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

**Answer:** Admitted.

6. Upon information and belief, Counterclaim-Defendant Warner Chilcott Company, Inc. (“WCCI”) is a corporation organized and existing under the laws of the Commonwealth of Puerto Rico, having a principal place of business at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

**Answer:** Admitted.

7. Upon information and belief, Counterclaim-Defendant Warner Chilcott (US), LLC (“WCUS”) is a limited liability corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 100 Enterprise Dr., Rockaway, New Jersey, 07866.

**Answer:** Admitted.

8. Upon information and belief, Counterclaim-Defendant Mayne Pharma International Pty. Ltd. (“Mayne”) is a corporation organized and existing under the laws of Australia, having a principal place of business at Level 21-390 St. Kilda Road, Melbourne, Australia 3004.

**Answer:** Admitted.

9. WCLI, WCCI, WCUS, and Mayne are collectively referred to herein as “Counterclaim-Defendants”.

**Answer:** The allegations in Paragraph 9 do not require a response. To the extent that a response is required, Plaintiffs/Counterclaim-Defendants admit the allegations in Paragraph 9.

**Answer to First Counterclaim**  
**(Declaratory Judgment of Invalidity of U.S. Patent No. 6,958,161)**

10. Counterclaim-Plaintiffs incorporate by reference their allegations in paragraphs 1-9 above.

**Answer:** Plaintiffs/Counterclaim-Defendants refer to and incorporate by reference their answers to Paragraphs 1-9, above.

11. Counterclaim-Defendants have asserted that Counterclaim Plaintiffs have infringed and are infringing the ‘161 patent.

**Answer:** Admitted that Plaintiffs/Counterclaim-Defendants have alleged that Mutual has infringed one or more claims of United States Patent No. 6,958,161 (the “‘161 patent”) by filing ANDA No. 91-043 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of generic Doxycycline Hyclate Delayed-Release Tablets 75 mg and 100 mg (“Mutual’s Proposed Drug Products”) before the expiration of the ‘161 patent. Admitted that Plaintiffs/Counterclaim-Defendants have alleged that Mutual’s Proposed Drug Products, if approved, will be administered to human patients for the treatment of infections, which administration constitutes direct infringement of the ‘161 patent. Denied in all other respects.

12. There is an actual, justiciable controversy between the parties concerning the validity of the '161 patent.

**Answer:** Admitted that there is a actual, justiciable controversy between the parties concerning the validity of the '161 patent, but denied that Defendants/Counterclaim-Plaintiffs are entitled to any relief.

13. U.S. Patent No. 6,958,161 ("the '161 patent") is invalid for failure to meet the Conditions of Patentability specified in 35 U.S.C. §§ 101, 102, 103, and/or 112.

**Answer:** Denied.

14. Accordingly, Counterclaim-Plaintiffs are entitled to a judgment declaring the '161 patent invalid.

**Answer:** Denied.

**Answer to Second Counterclaim**  
**(Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,958,161)**

15. Counterclaim-Plaintiffs incorporate by reference their allegations in paragraphs 1-9 above.

**Answer:** Plaintiffs/Counterclaim-Defendants refer to Plaintiffs/Counterclaim-Defendants' answers to Paragraphs 1-9.

16. Counterclaim-Defendants have asserted that Counterclaim Plaintiffs have infringed and are infringing the '161 patent.

**Answer:** Admitted that Plaintiffs/Counterclaim-Defendants have alleged that Mutual has infringed one or more claims of United States Patent No. 6,958,161 (the "'161 patent") by filing ANDA No. 91-043 under 21 U.S.C. § 355(j) for the purpose of obtaining

approval to engage in the commercial manufacture, use or sale of generic Doxycycline Hyclate Delayed-Release Tablets 75 mg and 100 mg (“Mutual’s Proposed Drug Products”) before the expiration of the ‘161 patent. Admitted that Plaintiffs/Counterclaim-Defendants have alleged that Mutual’s Proposed Drug Products, if approved, will be administered to human patients for the treatment of infections, which administration constitutes direct infringement of the ‘161 patent. Denied in all other respects.

17. Counterclaim-Plaintiffs seek a declaration that they do not infringe any valid claim of the ‘161 patent.

**Answer:** Plaintiffs/Counterclaim-Defendants admit that Counterclaim-Plaintiffs seek a declaration that they do not infringe any valid claim of the ‘161 patent, but deny that Counterclaim-Plaintiffs are entitled to any relief.

18. Accordingly, Counterclaim-Plaintiffs are entitled to a judgment declaring that they do not infringe any valid claim of the ‘161 patent.

**Answer:** Denied.

19. The “WHEREFORE” paragraph following paragraph 18 of the corrected Counterclaims and the four lettered paragraphs (a-b, d-e) that follow it state Mutual’s prayer for relief, to which no response is required. To the extent that a response is required, Plaintiffs/Counterclaim-Defendants deny the allegations set forth in the “WHEREFORE” paragraph following paragraph 18 of the corrected Counterclaims and the four lettered paragraphs (a-b and d-e) that follow it and deny that Mutual is entitled to any of the relief requested therein, or to any relief whatsoever.

20. Plaintiffs/Counterclaim-Defendants deny any and all allegations of the corrected Counterclaims not expressly admitted.

Respectfully submitted,

Dated: March 17, 2009

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that true copies of the foregoing papers were caused to be served on March 17, 2009 via ECF and/or email upon the following:

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